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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,339	03/12/2002	Peter Jungblut	028622-0108	1997

7590 04/22/2009
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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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04/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/890,339	Applicant(s) JUNGBLUT ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28August2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,45,48-57 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51,63,66 is/are allowed.
- 6) ☒ Claim(s) 44,45,48-50,52-57,64,65,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 August 2007 has been entered.

Claims 44, 51, 63 and 66 have been amended.

2. Claims 44, 45, 48-57 and 63-68 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 44, 45, 48-57 and 63-68 under 35 U.S.C. 112, second paragraph, as being indefinite for the sequence identity of the claimed nucleotides, is withdrawn in light of the amendment of the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 44, 45, 48-50 and 52-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

One embodiment of claim 44 is drawn to an isolated or purified nucleic acid molecule coding for a protein which is "a combination thereof" of the other listed proteins/fusion proteins. It is unclear what is meant by such a combination.

Art Unit: 1645

Does this mean that the embodiment is a single nucleic acid molecule which encodes SEQ ID NO:1 **plus** SEQ ID NO:2 **plus** fusion of SEQ ID NO:1 with an unknown protein **plus** fusion of SEQ ID NO:2 with an unknown protein **plus** SEQ ID NO:1 with SEQ ID NO:2?

Dependent claims 45, 48-50 and 52-57 depend from the claim, but do not clarify the issue.

6. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a composition comprising nucleic acid molecule further comprising, "optionally", a pharmaceutically acceptable carrier.

It is unclear what are the metes and bounds of the scope of the claim. Does the composition comprise said carrier, or does it not comprise said carrier? Thus, it is unclear what may be included or excluded from the claim.

7. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a composition comprising nucleic acid molecule further comprising, "optionally", suitable means for detection.

It is unclear what are the metes and bounds of the scope of the claim. Does the composition comprise said means for detection, or does it not comprise said means for detection? What is a "means of detection"? Thus, it is unclear what may be included or excluded from the claim.

Art Unit: 1645

8. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of preventing, ameliorating or treating a *M. tuberculosis* induced "disease". Dependent claim 55 states that the induced disease is tuberculosis. Therefor, it is unclear what are the metes and bounds of the types of *M. tuberculosis* induced "disease" being claimed in claim 54.

9. Claims 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: actual reagents and steps by which said polynucleotides are detected.

10. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a composition comprising nucleic acid molecule further comprising, "optionally", a pharmaceutically acceptable carrier.

It is unclear what are the metes and bounds of the scope of the claim. Does the composition comprise said carrier, or does it not comprise said carrier? Thus, it is unclear what may be included or excluded from the claim.

11. Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

The claim is drawn to a composition comprising nucleic acid molecule further comprising, "optionally", a pharmaceutically acceptable carrier.

It is unclear what are the metes and bounds of the scope of the claim. Does the composition comprise said carrier, or does it not comprise said carrier? Thus, it is unclear what may be included or excluded from the claim.

12. Claims 65 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

13. Claims 44, 45, 48-50, 52-57, 64, 65, 67 and 68 are rejected.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1645

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 22, 2009